How do I submit to the IRB?

All submissions should be routed using the University-wide IRB system, AURA. Please log in to the IRB module in AURA through the AURA website: http://aura.uchicago.edu

How do I select or determine the level of review?

Many new protocols require a full review, but if you believe your new research project qualifies for expedited review, please complete the Expedited Review section on the electronic submission form.

Alternatively, if you believe your study can be **exempted** from review, request "Exempt" review and fill out only those sections of the electronic submission form that appear in AURA. Please also upload any necessary documentation (e.g. a copy of the survey). The IRB office will then notify you if indeed your study qualifies as exempt or if you will need to complete the entire protocol submission form.

The IRB will make the final decision regarding level of review.

Incomplete submissions will not be reviewed until all necessary materials have been received regardless of the date the initial submission was received.

Is there a template available for a protocol document?

The BSD/UCMC IRBs require a protocol document to be submitted with all non-exempt new submissions. A sponsor protocol document used by multiple sites can be submitted, or, for a single-site study, the investigator should prepare a local protocol document. The protocol document, "protocol narrative," or "protocol" is submitted with the original submission of the protocol and revised versions, as necessary, with amendments. There is no required format, but the document must be sufficiently detailed to permit the IRB to evaluate the soundness of the procedures proposed and the potential risks and benefits to research subjects. The sample protocol narrative outline prepared by the IRB office demonstrates content that is generally requested by the IRB.

Protocol narrative outline

For **non-interventional** studies, such as chart reviews and specimen repositories, a sample template is also provided below:

Non Interventional Protocol Document

The OCR has templates for other protocol-related documents posted on the "Tools and Templates" page.

I am writing a new protocol and I need assistance in protocol design or determining number of subjects. Are there resources available?

The Biostatistics Clinic, part of the Biostatistics Laboratory in the Department of Public Health Sciences, offers free, short term statistical consultation. This might include discussion on protocol design, sample size calculations, or other assistance. For further information, please visit: https://health.uchicago.edu/research/biostatistics-laboratory .

What is Protected Health Information (PHI)?

Protected health information ("PHI") is any information that might directly or indirectly identify an individual, including

- Physical or mental health information
- Past, present, or future information
- Information collected, created or received
- Information in any medium: electronic, paper, oral

Inclusion of any of the below listed items, alone or in combination, is considered use of protected health information.

- Name – including the use of initials
- Address – All geographical identifiers smaller than a state, except for the initial three digits of a zip code
- Names of relative(s)
- Names of employer(s)
- Dates – any specific date, including date of discharge and date of birth, and including year-month combinations (year of event alone, without month or day, is not PHI)
- Telephone number
- Fax number
- E-mail address
- Social Security number
- Medical record number
- Health Plan or Account number
- Certificate or license number
- Vehicle or device serial number
- Web URL
- IP Address
- Voiceprints
- Fingerprints
- Photographs - full face
- Code
- Any other unique identifying number, characteristic, or code

I believe my study is exempt from IRB review. Can I go ahead?

Per local policy, the IRB reviewer must make the final determination regarding exemption status. **Never commence any study procedures until receiving notification of exemption or approval from the IRB**. Investigators should submit an exemption request through AURA with enough detail to determine whether the protocol meets exemption requirements. You should be notified within a week of the status of your exemption request.

If you make changes to an existing study that has previously been determined to be exempt, a new request for exemption should be submitted, as research activities may have changed such that the exempt requirements are no longer met.

Please contact the IRB staff for further information regarding specific studies that may be exempt from IRB review.

In addition, if you have received approval or exemption from a non-University of Chicago IRB, please contact the U of C IRB office to determine approval or exemption procedures at our site.